

AUTHORIZATION REQUEST FOR THE HOMEDIQ CORONAVIRUS (COVID-19) TEST

For In vitro Diagnostic Use
For use by people 18 years of age or older

INTENDED USE

The HomedIQ Coronavirus (COVID-19) Test is intended for the qualitative detection of nucleic acid from the SARS-CoV-2 in nasal swab specimens self-collected by individuals at home, using the HomedIQ COVID-19 Home Collection Kit, when determined by a healthcare provider to be appropriate based on results of a COVID-19 questionnaire (based on current testing guidelines within the Netherlands). Specimens collected using the HomedIQ Coronavirus (COVID-19) Home Collection Kit can be transported at ambient temperature for testing.

Testing is limited to Medische Laboratoria Dr. Stein and Collegae, which is a High Complexity ISO 15189 certified laboratory and meets the requirements to perform high complexity tests. Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in nasal swabs during the acute phase of infection. Positive results indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out a bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the Netherlands are required to report all positive results to the appropriate public health authorities (GGD/RIVM).

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information. Specimens that are self-collected will not be tested with an internal control to confirm that the specimen was properly collected. Self-collected specimens from SARS-CoV-2 positive individuals may yield negative results if the specimen was not collected properly.

DEVICE DESCRIPTION AND TEST PRINCIPLE

The HomedIQ COVID-19 Home Collection Kit enables the self-collection of a mouth and nasal swab sample that is then transported to the laboratory for RT-PCR testing for SARS-CoV-2. HomedIQ will contact all patients receiving positive and invalid test results. Patients with negative test results will be notified by email, phone message and through the website portal.

The HomedIQ COVID-19 Home Collection Kit includes a shipping box, pre-labelled return envelope, and a biohazard bag. Each HomedIQ COVID-19 Home Collection Kit is intended to be returned via Next Day shipping at ambient conditions on the same day of sample collection.

Specimens received at the clinical laboratory for testing will undergo review and accessioning prior to acceptance for testing.

The HomedIQ Coronavirus (COVID-19) Test will be performed at the Medische Laboratoria Dr Stein and Collegae High Complexity ISO 15189 certified laboratory. The Medische Laboratoria Dr Stein and Collegae uses the ROCHE COBAS 6800 & 8800 SYSTEMS per the Instructions for Use (without modification).

REAGENTS AND MATERIALS

HomedIQ Coronavirus (COVID-19) Home Collection Kit

1. Shipping box
2. Overpack with UN3373
3. Return Label (attached to polymailer)
4. Specimen biohazard bag with absorbent material
5. Mouth & Nasal swab & transport tube with transport media

(COBAS PCR MEDIA SWAB SAMPLE KIT, REF P/N: 07958021190)

MEDICAL OVERSIGHT AND PROCESS TO BE USED

HomedIQ will use an online eligibility questionnaire, based on current RIVM testing guidelines (<https://www.rivm.nl/en/novel-coronavirus-covid-19>) to determine whether a customer is eligible for a COVID-19 test. If a customer is determined to be eligible based on current RIVM testing guidelines, a prescription for testing is issued by a certified physician. Only after this step is completed the HomedIQ COVID-19 Home Collection Kit can be shipped to the customer's home.

In addition, the HomedIQ COVID-19 Home Collection Kit will be provided to members of particular payer and provider programs. HomedIQ is currently prioritizing programs which serve healthcare workers (e.g. insurance providers, emergency responder networks, etc.) and essential/critical workers (e.g. teachers, logistics and supply chain staff, electric company staff, pharmaceutical production staff). All members must be deemed eligible for the HomedIQ Coronavirus (COVID-19) Test, per the RIVM guidelines and relevant eligibility questionnaire, before a prescription for testing can be written and a test can be dispatched.

Patient Inclusion/Exclusion Criteria:

These criteria are based on current RIVM testing guidelines

Exclusion

- Anyone with severe symptoms
- People of any age with no symptoms
- People under and over 65 years with mild symptoms and comorbidity

Inclusion

- People of any age eligible for a test if they have any mild symptoms (cough, sore throat, muscle aches or body aches, vomiting or diarrhea, change in smell or taste, and shortness of breath).

Medisch Laboratoria Stein and Collegae Accessioning Criteria

All tests arriving at Medisch Laboratoria Stein and Collegae will be checked for the following deficiencies:

- Viral transport media leaked resulting in no sample for testing
- No swab and/or sample transport tube
- Kit not activated on homediq.com (sample held until Customer Care can reach patient and advise on activation)
- Accession date is greater than 48 hours from the return pick-up date for specimens tested with ROCHE COBAS 6800/8800 SYSTEMS
- Accession date is greater than 88 hours from the return pick-up date for specimens tested with ROCHE COBAS 6800/8800 SYSTEMS.

CONTROLS TO BE USED WITH THE HOMED-IQ COVID-19 HOME COLLECTION KIT

Each patient sample is run with the authorized ROCHE COBAS 6800 & 8800 SYSTEMS with applicable assay controls per manufacturer Instructions for Use, without any modification.

INTERPRETATION OF TEST RESULTS

All test controls should be examined prior to interpretation of patient results. If the controls are not valid, the patient results cannot be interpreted. The results interpretation algorithm for the Homed-IQ COVID-19 Home Collection Kit is based on the ROCHE COBAS 6800/8800 SYSTEMS. The algorithm is presented in Table 1.

Table 1. Results Interpretation Alg. SARS-CoV-2		
SARS-CoV-2	Interpretation	Lab Action
Positive	Valid sample	SARS-CoV-2 (+) result is valid and can be released
Negative	Valid sample	SARS-CoV-2 (-) result is valid and can be released
Invalid	Invalid Result. Repeat extraction and rRT-PCR. If the repeated result remains invalid, collect a new specimen from the patient	SARS-CoV-2 result is invalid and sample analysis is repeated

Patients receiving positive and invalid results will be contacted by the Homed-IQ Customer Service Team. Patients with negative test results will be notified by email, phone message and through the website portal. Patients will be receiving Patient Fact Sheets with their results. Patients with an invalid result will be receiving a second test kit.

In the case of positive results:

- Individuals will receive a phone call from the HomedIQ Medical Team and results will be released to the patient portal
- Results will be reported by HomedIQ to public health agencies (GGD/RIVM) as required

PERFORMANCE EVALUATION

1) Self-Collection Validation

Two usability studies were conducted by LGC to assess user interactions with the at-home Coronavirus (COVID-19) Test. In the first study, a total of 55 adults completed the study, of which 38% were over 60 years of age, 46% were between 40 - 59 years, and 16% were between 18 - 39 years old; 42% of participants were male and 58% were female. The majority (54/55) of participants produced self-collected nasal swabs that were received by the laboratory in a condition that was considered acceptable for testing. The majority of participants reported that they understood the Instructions provided for sample collection and packaging. Upon the completion of the first study, the Instructions for Sample Collection have been updated and a second usability study was undertaken. It included 33 participants of which 48% were over 60 years of age, 46% were between 40 - 59 years, and 6% were between 18 - 39 years old; 39% of participants were male and 61% were female. The study was conducted at a simulated at-home environment and the participants were observed during the sample collection and packing process.

All participants produced self-collected nasal swabs that were received by the laboratory in a condition that was considered acceptable for testing. No deviations from the Instructions for Use were noted by staff observing the sample collection.

All samples tested positive for human RNaseP gene (tested using authorized CDC 2019-Novel Coronavirus (2019-nCoV) kit) indicating that all participants successfully collected human biological material.

In addition to completed studies by others, HomedIQ Europe BV will submit a report to the RIVM (within 30 days) summarizing any testing performed with HomedIQ Coronavirus (COVID-19) Test including how many kits were requested and sent for home collection, how many kits were shipped and returned according to the instructions, how many specimens had to be rejected during accession and the main reasons for rejection, and the positivity rate of the first HomedIQ COVID-19 Home Collection Kit lot.

Conclusion: The HomedIQ Coronavirus (COVID-19) Test has demonstrated sample stability and usability that should be acceptable to the RIVM.

2) Human Gene Control Evaluation

Among 5,007 consecutive nasal swab samples self-collected using the COVID-19 Home Collection kit, 100% of the samples tested were found to contain the RNase P gene (cellularity rate of 100%; 95% CI: 99.9%, 100%). The mean and standard deviation of RNase P gene PCR Ct values were similar among sex, age group, race/ethnicity categories and comorbidities.

3) Analytical and Clinical Performance

The analytical and clinical performance of the ROCHE COBAS 6800 & 8800 SYSTEMS Assays including the COBAS SARS-CoV-2 & Influenza A/B Test has been demonstrated by ROCHE in the Emergency Use Authorization submission authorized on 03/16/2020 and 09/04/2020 respectfully and in all EU countries accepting the CE mark.

See link: <https://www.roche.com/media/releases/med-cor-2020-09-04.htm>

LIMITATIONS:

- Specimens that are self-collected will not be tested with an internal control to confirm that the specimen was properly collected. Self-collected specimens from SARS-CoV-2 positive individuals may yield negative results if the specimen was not collected properly;
- The requirement to run a sample adequacy control for all samples that were self-collected will be waived provided that the following disclosure has been acknowledged by the entity utilizing authorized home collection kits and a statement is included in the test reports for specific patients who self-collected a specimen:

Acknowledgements

1) (Insert Client name) acknowledges it has received the disclosure below:

Specimens that are self-collected will not be tested with an internal control to confirm that the specimen was properly collected. Self-collected specimens from SARS-CoV-2 positive individuals may yield negative results if the specimen was not collected properly.

2) Test Report Limitation

Specimens that are self-collected were not tested with an internal control to confirm that the specimen was properly collected. As such, unobserved self-collected specimens from SARS-CoV-2 positive individuals may yield negative results if the specimen was not collected properly.